Complete Summary

GUIDELINE TITLE

Quantitative ultrasound in the management of osteoporosis: the 2007 ISCD official positions.

BIBLIOGRAPHIC SOURCE(S)

Krieg MA, Barkmann R, Gonnelli S, Stewart A, Bauer DC, Del Rio Barquero L, Kaufman JJ, Lorenc R, Miller PD, Olszynski WP, Poiana C, Schott AM, Lewiecki EM, Hans D. Quantitative ultrasound in the management of osteoporosis: the 2007 ISCD official positions. J Clin Densitom 2008 Jan-Mar;11(1):163-87. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Primary osteoporosis (i.e., postmenopausal and osteoporosis associated with aging) and osteoporotic fractures

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Technology Assessment

CLINICAL SPECIALTY

Endocrinology
Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Radiology
Rheumatology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To address the clinical application of quantitative ultrasound for fracture risk assessment, diagnosis of osteoporosis, treatment initiation and monitoring, and quality assurance/control

TARGET POPULATION

Adults who have or may be at risk of primary osteoporosis (i.e., postmenopausal and osteoporosis associated with aging)

Note: The current recommendations apply only to patients with primary osteoporosis. Subjects with secondary osteoporosis or metabolic bone disease (e.g., glucocorticoid-induced osteoporosis, hyperparathyroidism, osteomalacia) should be managed according to good medical practice.

INTERVENTIONS AND PRACTICES CONSIDERED

Quantitative ultrasound (QUS)

- Fracture risk assessment
- Diagnosis of osteoporosis (not recommended for diagnosis according to World Health Organization standards)
- Treatment initiation
- Treatment monitoring (not recommended)
- Quality assurance/quality control

MAJOR OUTCOMES CONSIDERED

- Accuracy and precision of quantitative ultrasound for predicting osteoporotic fractures
- Bone mineral density: T-scores
- Fracture risk and incidence

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Task Force members performed a medical literature search relevant to the clinical and/or technical questions using a method modified from that utilized by the Cochrane reviews. The literature searches were conducted using electronic databases that included PubMed, EMBASE and MEDLINE. Appropriate articles were selected from the searches for further review.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence

Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The development of the International Society for Clinical Densitometry (ISCD) Official Positions was undertaken according to the RAND/UCLA Appropriateness method (RAM). This is a mechanism to determine whether procedures or indications are expected to provide a specific health benefit, designated as "appropriate," that exceeds the potential negative consequences by such a wide margin that the procedure or indication is worth doing, exclusive of cost. The rationale for use of the RAM for the PDC is based on its ability to combine the best available scientific evidence with the collective judgment of worldwide experts in the bone field, to yield appropriate recommendations that are patient- and technology- specific.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Position Development Conference (PDC) Expert Panel

Concurrent with Task Force work, international experts in the field of bone densitometry and societies specific to skeletal health were contacted by the PDC Steering Committee to serve as member panelists. Twelve experts agreed to participate on the PDC Expert Panel. In addition to individuals representing many regions of the world, official representatives from The American Society for Bone and Mineral Research (ASBMR), International Society for Bone and Mineral Research (IBMS), and the National Osteoporosis Foundation (NOF) were participants on the Expert Panel. The role of the Expert Panel was to review the proposed Official Positions and supportive documents developed by the task forces and make final recommendations to the International Society for Clinical Densitometry Board of Directors (ISCD BOD).

PDC Moderators

PDC panel Moderators with experience in the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were selected by the Steering Committee. Two moderators assisted the Chair of the PDC in the development and refinement of statements derived from the initial Task Forces questions and sub-questions and, along with the Chair of the PDC, lead the discussion and the rating by the Expert Panel during the PDC in Lansdowne, Virginia, USA, July on 20-22, 2007.

Grading of the Official Positions

All Official Positions for the 2007 PDC were rated by the Expert Panel in the following categories: appropriateness, necessity, quality of evidence, strength of recommendations and application of recommendations (see "Rating Scheme for the Strength of the Recommendations" for definitions).

Proposed ratings in all cases, except the RAM ratings for appropriateness and necessity for each of the above categories, were included in the preliminary Official Positions crafted by each Task Force. Final ratings were determined by the on site, convened Expert Panel that included appropriateness and necessity.

A rating of "appropriate" was required in order for a statement to be sent to the BOD for selection as an ISCD Official Position. Ratings of each Official Position from the 2007 PDC are expressed in the form of four characters representing quality of the evidence, strength of the recommendation, application of the recommendation, and whether it is necessary as previously described. For example, a rating "Good-A-W-Necessary" indicates that the evidence includes consistent results from well-designed, well-conducted studies in representative populations, a strong recommendation supported by the evidence, worldwide recommendation, and is necessary to perform in all instances. Since PDC topics are often selected because strong medical evidence is unavailable, it is the nature

of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, the ISCD Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

PDC Procedures

After the initial selection of topics by the Board of Directors and Scientific Advisory Committee, the PDC Steering Committee selected five Task Force chairpersons, one for each of the five major PDC topics. Thereafter, the PDC Steering Committee and Task Force chairpersons worked collectively to select international experts as members of their respective Task Forces with the knowledge required to evaluate their assigned PDC topic. All topic questions and sub-questions that were generated by each Task Force were thoroughly researched in the scientific medical literature.

Prior to the PDC meeting in Lansdowne, Virginia, USA, topic questions and sub-questions were converted into recommendation statements that were sent to the Expert Panel for an initial "appropriateness" rating. The PDC required a median "appropriateness" rating in either the upper third or lower third of the rating continuum (continuum was 1 to 9 with clusters 7 to 9 representing the upper third and clusters 1 to 3 representing the lower third) without "disagreement." "Disagreement" was defined as lack of consensus being predetermined to be four or more Expert Panelists rating in extreme clusters 1 to 3 and 7 to 9. In circumstances where the median "appropriateness" rating was less than 7, no Official Position was developed.

In making its decisions, the Expert Panel considered the level of the medical evidence, expert opinion and the clinical need for a recommendation. In some instances, regulatory issues received consideration. The statements rated as "appropriate" with a median score of 7 or higher without "disagreement" by the Expert Panel were designated Official Positions. The statements rated as "uncertain" with a median score between four and six or any median score with "disagreement" were further discussed at the PDC.

After the initial rating the documents supporting all Task Forces' recommendations were sent to the Expert Panelists for review. In brief, Task Force chairs presented reports on their topics supporting the "uncertain" statements to the Expert Panelists in closed session on the first day of the conference. These statements were then edited by Task Force chairs, if necessary, reflecting suggestions made by the Expert Panelists. Re-rating of "uncertain" statements occurred during each Task Force chairpersons' presentation when the PDC Moderators felt there was a significant likelihood of change in the opinions of the Expert Panel.

After all statements rated as "appropriate without disagreement" had been selected and all supporting evidence presented, the Expert Panel performed a final rating for necessity, quality of the evidence, strength of the recommendation, and application of the recommendation. The following day, the proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public and attended by ISCD members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were

encouraged to provide comments and suggestions to the expert panelists. On the third day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

All Official Positions for the 2007 Position Development Conference were rated by the Expert Panel in the following categories:

1. **Appropriateness**: Statements that the Expert Panel rated as "appropriate without disagreement" according to predefined criteria derived from the RAND/University of California, Los Angeles (UCLA) Appropriateness Method (RAM) were referred to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) with a recommendation to become ISCD Official Positions. A statement was defined as "appropriate" when the expected health benefit exceeded the expected negative consequences by a significant margin such that it was worth performing.
2. **Necessity**: Recommended Official Positions that were rated by the Expert Panel were then rated according to necessity to perform in all circumstances, i.e., whether the health benefits outweighed the risks to such an extent that it must be offered to all patients. Necessity rating was conducted in a similar fashion as the appropriateness rating, in that each Official Position had to be rated as necessary without disagreement using similar predefined RAM criteria.
3. **Quality of evidence**:

   Good: Evidence includes consistent results from well-designed, well-conducted studies in representative populations.

   Fair: Evidence is sufficient to determine effects on outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies.

   Poor: Evidence is insufficient to assess the effects on outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

4. **Strength of recommendations**:

   A. Strong recommendation supported by the evidence

   B. Recommendation supported by the evidence

   C. Recommendation supported primarily by expert opinion

5. **Application of recommendations**:

   W: Worldwide recommendation

   L: Application of recommendation may vary according to local requirements

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The proposed Official Positions with supportive evidence were presented by the Task Force chairs at a meeting open to the public and attended by International Society for Clinical Densitometry (ISCD) members, representatives from companies with interests in bone health and skeletal assessment, and other individuals with interest in bone disease and densitometry. All participants were encouraged to provide comments and suggestions to the expert panelists. On the third day, the Expert Panelists, in closed session, determined final wording of the proposed Official Positions.

Following completion of the Position Development Conference, the Steering Committee finalized recommendation wording without changing content. These recommendations were then presented to the International Society for Clinical Densitometry Board of Directors (ISCD BOD) for review and voting. The BOD did not alter the content or wording of the proposed Official Positions. Recommendations approved by a majority vote of the ISCD BOD became ISCD Official Positions.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC) and the International Society for Clinical Densitometry (ISCD): The full list of positions from the ISCD is provided in '2007 Official Positions & Pediatric Official Positions' (see the "Availability of Companion Documents" field).

Definitions for the quality of evidence (good, fair, poor), strength of recommendations (A-C), application of recommendations (W, L), and appropriateness/necessity are presented at the end of the "Major Recommendations" field.

Technological Diversity Amongst Quantitative Ultrasounds (QUS) Devices

ISCD Official Position

- For QUS, bone density measurements from different devices cannot be directly compared.

Grade: Good-A-W-Necessary

Can QUS Be Used for Fracture Risk Assessment?

ISCD Official Positions

- The only validated skeletal site for the clinical use of QUS in osteoporosis management is the heel.

  Grade: Good-A-W-Necessary

- Validated heel QUS devices predict fragility fracture in postmenopausal women (hip, vertebral and global fracture risk) and men over the age of 65 (hip and all non-vertebral fractures), independently of central dual-energy X-ray absorptiometry (DXA) bone mineral density (BMD).

  Grade: Good-A-W-Necessary

- Discordant results between heel QUS and central DXA are not infrequent and are not necessarily an indication of methodological error.

  Grade: Good-A-W-Necessary

- For QUS, different devices should be independently validated for fracture risk prediction by prospective trials or by demonstration of equivalence to a clinically validated device.

  Grade: Good-B-W-Necessary

Can QUS Be Used to Diagnose Osteoporosis?

ISCD Official Position

- The World Health Organization (WHO) diagnostic classification cannot be applied to T-scores from measurements other than DXA at the femur neck, total femur, lumbar spine or one-third (33%) radius because those T-scores are not equivalent to T-scores derived by DXA.

  Grade: Good-A-W-Necessary

Can QUS Be Used to Initiate Treatment?

ISCD Official Positions

- Central DXA measurements at the spine and femur are the preferred method for making therapeutic decisions and should be used if possible. However, if central DXA cannot be done, pharmacologic treatment can be initiated if the fracture probability, as assessed by heel QUS using device specific thresholds and in conjunction with clinical risk factors, is sufficiently high.

Grade: Fair-C-W-Necessary

- Heel QUS in conjunction with clinical risk factors can be used to identify a population at very low fracture probability in which no further diagnostic evaluation may be necessary.

  Grade: Good-B-W-Necessary

Can QUS Be Used to Monitor Treatment?

ISCD Official Position

- QUS cannot be used to monitor the skeletal effects of treatments for osteoporosis.

  Grade: Good-A-W-Necessary

QUS Reporting

ISCD Official Positions

- For QUS, the report should combine the following standard elements:
  - Date of test
  - Demographics (name, date of birth or age, sex)
  - Requesting provider
  - Names of those receiving copy of report
  - Indications for test
  - Manufacturer, and model of instrument and software version
  - Measurement value(s)
  - Reference database
  - Skeletal site/region of interest
  - Quality of test
  - Limitations of the test including a statement that the WHO diagnostic classification cannot be applied to T-scores obtained from quantitative computed tomography (QCT), peripheral (p)QCT, QUS, and pDXA (other than one-third (33%) radius) measurements
  - Clinical risk factors
  - Fracture risk estimation
  - A general statement that a medical evaluation for secondary causes of low BMD may be appropriate
  - Recommendations for follow-up imaging

  Grade: Fair-C-W-Necessary

- For QUS, the report may include the following optional item:
  - Recommendations for follow-up imaging Recommendations for pharmacological and non pharmacological interventions.

  Grade: Fair-C-W

What Are the Quality Assurance and Quality Control (QA/QC) Criteria for QUS?

ISCD Official Positions

- For QUS, device-specific education and training should be given to the operators and interpreters prior to clinical use.

  Grade: Good-A-W-Necessary

- Quality control procedures should be performed regularly.

  Grade: Good-A-W-Necessary

Definitions:

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2. **Necessity**: Recommended Official Positions that were rated by the Expert Panel were then rated according to necessity to perform in all circumstances, i.e., whether the health benefits outweighed the risks to such an extent that it must be offered to all patients. Necessity rating was conducted in a similar fashion as the appropriateness rating, in that each Official Position had to be rated as necessary without disagreement using similar predefined RAM criteria.
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4. **Strength of recommendations**:

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B. Â Recommendation supported by the evidence

C. Â Recommendation supported primarily by expert opinion

5. **Application of recommendations**:

W: Worldwide recommendation

L: Application of recommendation may vary according to local requirements

CLINICAL ALGORITHM(S)

The original guideline document contains an algorithm titled "Example of a Case-Finding Strategy if Dual-Energy X-ray Absorptiometry (DXA) Is Not Available."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is specifically stated for each recommendation (see "Major Recommendations" field).

Since the field of bone densitometry is new and evolving, some clinically important issues that are addressed at the Position Development Conferences are not associated with robust medical evidence. Accordingly some Official Positions are based largely on expert opinion.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate clinical application of quantitative ultrasound for fracture risk assessment, diagnosis of osteoporosis, treatment initiation and monitoring

POTENTIAL HARMS

False positive and false negative results of quantitative ultrasound

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Since Position Development Conference topics are often selected because strong medical evidence is unavailable, it is the nature of the process that Official Positions are not always supported by the highest possible level of evidence. Nevertheless, theÂ International Society for Clinical Densitometry (ISCD) Official Positions encourage consistent approaches in the clinical practice of bone densitometry, and focus attention on issues that require further study.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy included publication of the International Society for Clinical Densitometry (ISCD) Official Positions in international journals that directly or indirectly pertain to skeletal diseases and the measurement of skeletal health.

Formal presentation of the ISCD Official Positions occurs at ISCD Annual Scientific Meetings, all ISCD Adult and Pediatric Bone Density Educational Courses, and ISCD Vertebral Fracture Assessment Educational courses. The Official Positions have been published in the society's official journal, Journal of Clinical Densitometry and Assessment of Skeletal Health.

IMPLEMENTATION TOOLS

Clinical Algorithm
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Krieg MA, Barkmann R, Gonnelli S, Stewart A, Bauer DC, Del Rio Barquero L, Kaufman JJ, Lorenc R, Miller PD, Olszynski WP, Poiana C, Schott AM, Lewiecki EM, Hans D. Quantitative ultrasound in the management of osteoporosis: the 2007 ISCD official positions. J Clin Densitom 2008 Jan-Mar;11(1):163-87. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Mar

GUIDELINE DEVELOPER(S)

International Society for Clinical Densitometry - Private Nonprofit Organization

SOURCE(S) OF FUNDING

International Society for Clinical Densitometry

GUIDELINE COMMITTEE

Quantitative Ultrasound in the Management of Osteoporosis Task Force

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Financial support for the 2007 Position Development Conference (PDC) was received in the form of unrestricted grants from The Alliance for Better Bone Heath (P&G Pharmaceuticals & Sanofi-Aventis Pharmaceuticals), Amgen Pharmaceuticals, Eli Lilly & Company, Hologic, Inc., Merck Human Health, and Wyeth Pharmaceuticals. These grantors had no role in the selection of PDC topics, participants or ratings for the final International Society of Clinical Densitometry (ISCD) Official Positions.

ENDORSER(S)

American Association of Clinical Endocrinologists - Medical Specialty Society
American Society for Bone and Mineral Research - Professional Association
National Osteoporosis Foundation - Disease Specific Society
The Endocrine Society - Disease Specific Society
The North American Menopause Society - Private Nonprofit Organization

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Journal of Clinical Densitometry.

Print copies: Available from the International Society for Clinical Densitometry, 342 North Main St., West Hartford, CT 06117-2507; Phone: (860) 586-7563; Fax: (860) 586-7550; Website: www.iscd.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- 2007 official positions of the International Society for Clinical Densitometry. 2007 Oct. 14 p. Electronic copies: Available in Portable Document Format (PDF) from the International Society for Clinical Densitometry Web site.
- 2007 official positions & pediatric official positions of the International Society for Clinical Densitometry. 2007 Oct. 17 p. Electronic copies: Available in Portable Document Format (PDF) from the International Society for Clinical Densitometry Web site.
- Official positions of the International Society for Clinical Densitometry and executive summary of the 2007 ISCD Position Development Conference. 2008. 17 p. Electronic copies: Available in Portable Document Format (PDF) from the International Society for Clinical Densitometry Web site.

Print copies: Available from the International Society for Clinical Densitometry, 342 North Main St., West Hartford, CT 06117-2507; Phone: (860) 586-7563; Fax: (860) 586-7550; Website: www.iscd.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI InstituteÂ on July 24, 2009. The information was verified by the guideline developer on September 15, 2009.

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